Overview of Chlorsulfuron Risk Assessment

August 9, 2004

Introduction

This document summarizes the Environmental Protection Agency's (EPA or the Agency) revised human health and ecological risk findings and conclusions for the sulfonylurea pesticide chlorsulfuron, as presented fully in the preliminary risk assessment documents, "*Chlorsulfuron: Occupational and Residential Exposure and Risk Assessment/Characterization for Reregistration Eligibility Decision Document and the Proposed use on Pasture and Rangeland Grasses"* dated July 1, 2002, and "*Environmental Fate and Ecological Risk Assessment for Chlorsulfuron*" dated March 18, 2003. Chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This action established new tolerances for residues for chlorsulfuron in or on grass, forage and grass hay. This action also reassessed all other existing tolerances of chlorsulfuron as required by the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA). Therefore, this overview and the supporting risk assessments address only the environmental and occupational risks from the use of chlorsulfuron. For information on dietary and residential risks, please refer to the earlier notice published in the *Federal Register*.

The purpose of this overview is to help the reader identify the key features and findings of these risk assessments and better understand EPA's conclusions. EPA developed this overview in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to differing formats.

Use Profile

Chlorsulfuron (2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzenesulfonamide) is used as a pre- and post-emergent herbicide to control a variety of weeds on cereal grains, pasture and rangeland, industrial sites, and turf grass.

Based on available usage information for the years 1988 through 1999, the Agency estimates that chlorsulfuron usage averaged approximately 72,000 pounds of active ingredient per year to treat over 5.5 million acres. Its largest markets in terms of total pounds active ingredient are winter wheat (90%) and spring wheat (5%). The remaining usage is primarily on barley, oats, fallow fields and pasture/hay. Crops with a high percentage of the total U.S. planted acres treated include winter wheat (11%) and oats (2%), while registered sites with little or no usage include lawn and ornamental turf. Most chlorsulfuron usage is in California, Idaho, Kansas, Minnesota,

North Dakota, Oklahoma, Oregon, South Dakota, Texas, and Washington. Data are not yet available for the new use on pastures and rangelands that EPA approved in 2002; however, chlorsulfuron is reportedly used in these areas by the US Department of Interior (Bureau of Land Management) to control invasive weed species.

- Technical Registrant. E.I. duPont de Nemours Company.

- Agricultural Uses. Chlorsulfuron is used in agriculture to control weeds on terrestrial food crops, including grain crops (e.g., wheat, barley and oats). It is also used on pasture, rangelands, and ornamental lawns and grasses.

- Residential Uses. Chlorsulfuron is used by homeowners as a spot treatment on lawns, however, usage data from 1988 to 1999 show little or no usage on lawns.

- Formulations. Chlorsulfuron is formulated as water-dispersible granules.

- Methods of Application. Chlorsulfuron is typically applied using ground, hand-held or aerial equipment. Ground equipment includes groundboom, while hand-held equipment includes backpack sprayer and low-pressure handwand for spot treatments.

- Application Rates. Chlorsulfuron rates vary depending on the use site. For grain crops, maximum seasonal rates range from 0.0078 to 0.023 pounds active ingredient per acre. For pasture and rangeland, rates range from 0.012 to 0.0625 pounds active ingredient per acre. The use on turf and ornamentals has the highest maximum seasonal application rate, ranging from 0.26 to 0.5 pounds active ingredient per acre.

Human Health Risk Assessment

Dietary and Residential Risks

The risks from exposure to chlorsulfuron from dietary (food and water) and residential uses are not included here. As mentioned earlier, these risks were assessed when the Agency registered a new use on range and pasture lands and reassessed the other existing tolerances. This process concluded that there is reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to chlorsulfuron residues from food, drinking water or residential uses.

For a complete discussion of these risks and the subsequent decision, please see the notice published on August 14, 2002, in the *Federal Register* (volume 67, number 157). This action established new tolerances for residues of chlorsulfuron in or on grass, forage and grass hay and reassessed all other existing tolerances in accordance with the FFDCA, as amended by the FQPA.

Occupational Risk

- The occupational risk assessment addresses risks to pesticide workers who may be exposed to chlorsulfuron when mixing, loading, or applying a pesticide (i.e., handlers).

- EPA assessed the occupational risks for chlorsulfuron using the following:

  - The uncertainty factor (UF) is 100X for occupational risk, based on a 10X for standard uncertainties in applying animal studies to humans (inter-species extrapolation) and a 10X for varying effects among individuals (intra-species variability). The occupational assessment does not consider an FQPA Safety Factor for sensitive populations (infants or children).

  - For short-term dermal and inhalation exposure, the No Observed Adverse Effect Level (NOAEL) is 75 mg/kg/day from a developmental toxicity study in rabbits. Decreases in body weight gain were observed at a Lowest Observed Adverse Effect Level (LOAEL) of 200 mg/kg/day.

  - Because the Agency found that chlorsulfuron has no evidence of carcinogenicity, a cancer risk assessment was not conducted.

- The Agency did not conduct a post-application exposure assessment because chlorsulfuron is used early in the growing season and there is little worker activity in the crops where chlorsulfuron is used.

- A margin of exposure (MOE) of 100 is considered adequately protective for all occupational exposures to chlorsulfuron; therefore, an MOE greater than 100 is not of concern.

<u>Use Scenarios</u>

- The Agency identified 11 major occupational exposure scenarios based on the equipment and techniques expected to be used to apply chlorsulfuron. These scenarios represent short-term (1 to 28 days) exposures. Based on the use pattern and site information, no intermediate- or long-term exposure is expected.

- At the baseline level of protection (i.e., long-sleeved shirt and long pants, shoes, socks, no respiratory protection and no chemical-resistant gloves) all MOEs are greater than 100. Therefore, risks are below EPA's level of concern and no additional levels of protection were considered in the risk assessment. Not all registered labels contain these personal protective equipment requirements at this time.

- The unit exposure values (milligram of active ingredient exposure/pounds handled) used in this assessment were based on the Pesticide Handlers Exposure Database Version 1.1 (PHED, 1998) and standard assumptions for handler exposure. There were no chemical-specific data available for chlorsulfuron to assess potential exposure to workers.

Risk Summary

- Only short-term risks were assessed because intermediate- and long-term exposure is not expected based on the use pattern of chlorsulfuron.

- All route-specific and combined MOEs are greater than the target MOE of 100 and therefore risks are not of concern (MOEs range between 1,000 and 56,000).

- No post-application exposure is expected from the use of chlorsulfuron; therefore, the Agency did not assess risk to workers from post-application exposure.

Ecological Risk Assessment

To estimate potential ecological risk, EPA integrates exposure and ecotoxicity information using the quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic exposure estimates by ecotoxicity values for various wildlife species. RQs are then compared to levels of concern (LOCs); the higher the RQ, the greater the potential risk.

Environmental Fate Information

Chlorsulfuron is persistent and highly mobile in the environment and may be transported by runoff or spray drift. Degradation by hydrolysis appears to be the most significant mechanism for degradation of chlorsulfuron, but is only significant in acidic environments (23 day half-life at pH = 5); chlorsulfuron is stable to hydrolysis at neutral to high pH. Degradation half-lives in soil environments were quite variable and ranged from 14 to 320 days. Chlorsulfuron has a low potential to bioaccumulate.

Non-target Terrestrial Animal Risk

- The use of chlorsulfuron is not expected to pose an acute or chronic risk to avian species. Acute and chronic RQs are less than 0.01 and are significantly below the Agency's LOC for birds. Chlorsulfuron is practically non-toxic to birds on an acute basis. On a chronic basis, effects included reduced growth, survival and reproduction (lower number of viable embryos).

- The use of chlorsulfuron is not expected to pose an acute or chronic risk to mammalian species. Acute and chronic RQs are less than 0.01 and are significantly below the Agency's Level of Concern (LOC) for mammals. Chlorsulfuron exhibited low acute and chronic toxicity in laboratory studies on rats.

- Although chlorsulfuron risks resulting from direct acute and chronic exposure to terrestrial animals are expected to be low, terrestrial animals may be affected by an adverse impact on plants and plant communities.

Non-target Aquatic Animal Risk

- Acute and chronic RQs for aquatic animals are all less than 0.01 and do not exceed the LOC for freshwater or marine/estuarine fish and invertebrates.

Non-target Plant Risk

- EPA is concerned about the risk to non-target plants from both drift and exposure to contaminated water.

- Chlorsulfuron can harm plants when absorbed by roots or foliage. Chlorsulfuron exposure may cause visible effects, such as death, in days or weeks; or it may cause delayed effects on fruit and seed production observable several weeks or months after exposure. Symptoms vary, depending on the sensitivity of the plant and the magnitude of exposure.

- Vegetative vigor and seedling emergence studies were used to screen risks for non-target and endangered plants.
  - Repeated vegetative vigor studies have recently been submitted to the Agency because the earlier studies did not establish a NOAEL. These studies will be reviewed and considered before the Agency makes a decision regarding chlorsulfuron's eligibility for reregistration.

Risks to Non-target Plants from Drift and Runoff

- Some researchers have concluded that small quantities of chlorsulfuron, such as might be found in airborne particles traveling long distances, may affect plant reproduction without altering vegetative growth.
  - Plant reproductive processes may be more sensitive to chlorsulfuron than growth effects.
  - Reproductive effects are difficult to recognize and trace to chlorsulfuron because reduced yield may occur below the detection level of conventional chemical analysis.

- To estimate non-target risk from spray drift exposure, 1% of the application was assumed for assessing risk from ground equipment applications and 5% for aerial equipment applications.

- When runoff was included in the RQ calculations, exposure was assumed to be 5% of the application based on chlorsulfuron's solubility.

- Risks to plants from drift and runoff are summarized in Table 1 below. RQs for both endangered and non-endangered species exceed levels of concern (i.e., greater than 1.0).

Table 1. Risk Quotients to Plants from Drift and Runoff (LOC is 1.0)

Crop Scenario: application	Aquatic Plants[1] (runoff only)		Semi-aquatic Plants[2] (drift and runoff)		Terrestrial Plants[3] (drift and runoff)		Terrestrial Plants[4] (drift and no runoff)	
	Non-target	Endan-gered	Non-target	Endan-gered	Non-target	Endan-gered	Non-target	Endan-gered
Turf: ground	17 - 21	26 - 31	N/A	N/A	24 - 45	106 - 203	30 - 58	2630 - 5040
Grains: ground	12 - 16	18 - 23	267 - 383	1200 - 1725	31 - 45	141 -203	40 - 58	3507 - 5040
Grains: aerial			288 - 413	1294 - 1860	52 - 75	235 - 338	200 - 290	17533 - 25202
Past./Range: ground	Not Assessed		1042	4688	123	551	156	13698
Past./Range: aerial	Not Assessed		1123	5056	204	919	800	68488
Non-crop (industrial) ground	Not Assessed		2333	10500	275	1235	350	30683

[1] PRZM/EXAMS was used to estimate peak Estimated Environmental Concentrations (EECs).

[2] Runoff modeled from ten-acre application site to one-acre adjacent wetland, using seedling emergence toxicity data based on a single application

[3] Runoff modeled from one-acre application site to adjacent one-acre terrestrial area, using seedling emergence toxicity data based on single application

[4] Drift from one-acre application site to one-acre adjacent terrestrial area, using vegetative vigor toxicity data based on single application

Risks to Plants from Exposure to Contaminated Irrigation Water

- Ground and surface water modeling indicate that irrigation water from groundwater or surface water sources, in areas with repeated chlorsulfuron use, may contain levels of chlorsulfuron high enough to adversely effect non-target plants and sensitive agricultural crops.

- Risk quotients estimate risk to plants in semi-aquatic areas adjacent to irrigated fields, terrestrial areas adjacent to irrigated fields, and sensitive crops within agricultural fields (such as soybeans, sugarbeets, and onions).

- Table 2 presents the estimated risks to plants from exposure to contaminated irrigation water. Irrigation with water containing chlorsulfuron exceeds risk LOCs for all plants in adjacent wetlands and for sensitive crops that may be exposed.

Table 2. Risk Quotients for Plants from Contaminated Irrigation Water (LOC is 1.0)[1]

	Non-target plant species		Endangered plant species	
	Surface Water Irrigation	Ground Water Irrigation	Surface Water Irrigation	Ground Water Irrigation

Semi-aquatic and terrestrial areas adjacent to irrigated fields[2]	17	4.5	1481	395
Sensitive Ag Crops in irrigated fields	341	91	N/A[3]	N/A[3]

[1] Assumes a single exposure to irrigation water containing chlorsulfuron

[2] Assumes 5% drift of contaminated irrigation water onto adjacent wetlands and no runoff of irrigation water.

[3] Not applicable, it is assumed that there are no endangered plants within agricultural fields that are irrigated.

Non-target Plant Incidents

- There are three reported incidents attributed to offsite drift of chlorsulfuron. In all three incidents, growers contended that applications of chlorsulfuron were responsible for damage to crops that were exposed to drift of the pesticide offsite.

- Determining the cause of plant damage is difficult because many symptoms of toxicity in plants appear similar to disease and nutrient deficiencies.

- Chlorsulfuron may adversely effect plant growth and reproduction at such low levels that detecting residues in plant tissues or in soil samples may be extremely difficult or impossible using conventional analytical methods.

Risks to Endangered Species

- **Birds and mammals.** Acute and chronic RQs for birds and mammals, including endangered species, are below the Agency's LOC.

- **Aquatic animals.** Acute and chronic RQs for aquatic animals, including endangered species, are below the Agency's LOC.

- **Plants.** Screening level deterministic RQs for direct effects to endangered plants far exceed the endangered species LOC. For aquatic plants, RQs for endangered species range from 18 to 31. For endangered plants in wetlands, RQs range from 1200 to 10500. RQs for endangered terrestrial plants range from 106 to 68,488.
  - RQs were calculated based on drift and runoff. Risk from direct application to endangered plants in pastures or rangeland is expected to be higher.

- Chlorsulfuron was included in the small grains cluster consultation with the Fish and Wildlife Service (FWS) that was completed in 1984; however, the Biological Opinion only considered risks to aquatic and terrestrial animals (not endangered plants).

How the Risk Picture May Change

- The Agency will review recently submitted vegetative vigor studies and, provided they meet guideline requirements, incorporate these results into the risk assessment. However, the Agency does not expect these results to alter the conclusions of this assessment.

- Additional studies, such as a plant toxicity study simulating far field spray drift exposure to exposing plants to relatively few concentrated droplets of herbicide, may refine the risk estimates for plants exposed to chlorsulfuron drift

- Additional plant toxicity studies could refine the Agency's risk assessment for plants exposed to contaminated irrigation water by comparing the effects from low concentrations of chlorsulfuron in an inch of simulated irrigation water with the effects demonstrated in the vegetative vigor and seedling emergence studies that have already been conducted.

Endangered Species Considerations

- The Agency will further refine the risk assessment for endangered/threatened plants before making a decision on the reregistration eligibility of chlorsulfuron.

- Further analysis of the overlap of individual species with each use site is required prior to determining the likelihood of potential impact to listed species.

- The Office of Pesticide Programs recently published on its web site (http://www.epa.gov/espp/consultation/index.html), an overview of our ecological risk assessment process for threatened and endangered species. Because of the timing of that document, the process described therein was not fully utilized for this screening-level endangered species risk assessment. The Agency will reassess the potential risk of chlorsulfuron use to endangered species using the new process at a later date and consult as appropriate with the U. S. Fish and Wildlife Service or National Marine Fisheries Service at that time.

Possible Risk Mitigation Measures

- Because of the significant risk to non-target plants, the Agency anticipates mitigation measures may still be needed after the risk assessment has been further refined.

- Possible measures include improving product labels to specify:
  - Maximum application rates
  - Numbers of application
    - assessments assume one per year, more frequent applications would increase risks
  - Methods of application

- Measures that may be proposed to control spray drift include:
  - Specifications on droplet size (large droplet size decreases drift)
  - Reducing the release height
  - Implementing wind speed restrictions (slow winds cause less drift)
  - Disallowing aerial applications
  - Disallowing applications during stable atmospheric conditions (*e.g.* temperature inversion)

- Measures that may be proposed to control runoff include:
  - Vegetative buffer zones

- Measures to reduce exposure to contaminated irrigation water, such as restricting use of tailwater so that it cannot be used to irrigate other crops.